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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,655	03/25/2004	Zhonglin Hao	00497-09	8524

34444 7590 10/19/2005

UNIVERSITY OF VIRGINIA PATENT FOUNDATION  
250 WEST MAIN STREET, SUITE 300  
CHARLOTTESVILLE, VA 22902

EXAMINER
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ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/809,655

Applicant(s)

HAO ET AL

Examiner

Agnes B. Rooke

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10, 11, 15-18 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 18, 30-32 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This final action is in response to the Applicant's reply filed on 08/15/2005.

Claims 10-11, 15-18, and 30-32 are pending.

Claims 15-17 are withdrawn. Claims 1-9, 12-14, and 19-29 are canceled.

Claim 32 was added.

Claims 10, 11, 18, 30, 31 and 32 are currently under examination.

This application is a divisional of 10/181,642, filed on 07/19/2002, now patent 6,924,121, which is a 371 of PCT/US01/01717, filed on 01/19/2001, which claims priority to 60/176,885, filed on 01/19/2000.

### **Rejections Withdrawn**

Rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Kokolus et al. (U.S. 5,807,978) is withdrawn.

***All new Rejections and Objections have been necessitated by the Applicants' amendments.***

### **Rejections Maintained**

#### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 18, and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 10, the Applicants claim an amino acid sequence that differs from SEQ ID NO:9 by a single mutation, wherein the single mutation represents a single amino acid deletion, insertion or substitution. This statement does not satisfy the written description requirement because the structure of the amino acid with its mutation(s) is not provided, and therefore the structure of the amino acid does not correlate with its function. Also, the place of the mutation should be specified.

Applicants amended claim 10 by adding the word "bioactive" and traverse the rejection of claim 10 on the grounds that: 1) the use of the term mutation is clear since the term is adequately described in the specification; 2) that the skilled in the art would have understood the term mutation based upon the disclosure provided in the specification as filed, and knowledge available at the time the application was filed; and 3) that the inventors had possession of the present invention as claimed in amended claim 10 and new claim 32, where as stated in specification a bioactive fragment of SAMP32/SEQ ID NO:9 encompasses natural or synthetic portions of the polypeptide that is capable of specific binding to at least one of the natural ligands of the native polypeptide. Therefore, Applicants state that they have specified a distinguishing attribute of the members of the claimed genus, since all members must bind to a ligand

that binds to the original sequence. Further, the Applicant state that they do not claim all "variants" of SEQ ID NO:9, but rather minor altered forms of SEQ ID NO:9 that have requisite functionality.

Examiner respectfully disagrees and states that the rejection stands because any amino acid sequence could act as a "bioactive" compound, and that claim 10 as currently stated, encompasses any bioactive amino acid sequence that differs from SEQ ID NO:9 by a single mutation, wherein a single mutation represents a single amino acid deletion, insertion or substitution. Thus, the Applicants did not describe all possible mutations present in claimed bioactive amino acid sequence that differs from SEQ ID NO:9 by these different mutations. Further, the word "bioactive" does not overcome the rejection because any amino acid sequence could have a bioactive function in itself.

Claim 18 was amended to state that "An antigenic composition comprising bioactive polypeptide of claim 10, and a pharmaceutically acceptable carrier. However, the amendment does not overcome the rejection because the structure of the amino acid with its mutation(s) is not provided, and therefore the structure of the amino acid does not correlate with its function. Thus, the rejection of claim 18 stands.

In claim 30 the Applicant refers to a fragment of SEQ ID NO:9, but a fragment of an amino acid sequence could be, for example, an active lysine. The claims do not satisfy the written description requirement because the fragment of SEQ ID NO:9 is

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not specifically provided, and thus the structure of the polypeptide does not correlate with its function.

Applicants responded that they amended claim 30 by adding the term "bioactive" and therefore overcame the rejection of claim 30.

Examiner disagrees, because the sequence of "a bioactive fragment of SEQ ID NO:9" is still not disclosed, and adding the word "bioactive" to a fragment, does not overcome the rejection, since an undisclosed sequence of a fragment or a bioactive fragment is still not properly described in the written description. Also, if the structure of a fragment of a sequence is unknown, thus its function cannot be ascertained.

Further, on pages 8 and 9 of the Remarks, the Applicants' argue against the rejection under 35 U.S.C. 112, second paragraph, where none such rejection was submitted by examiner. Therefore, the arguments regarding 35 U.S.C. 112, second paragraph are not considered.

**New Rejection to the new claim 32**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 32, the Applicant claims an amino acid sequence that differs from SEQ ID NO:9 by a single mutation, wherein the single mutation represents a single amino acid deletion, insertion or substitution. This statement does not satisfy the written description requirement because the structure of the bioactive amino acid sequence with its mutation(s) is not provided, and therefore the structure of the amino acid does not correlate with its function. Also, the place of the mutation should be pointed out.

### ***Objections to Claims***

Claim 11 is objected to because it depends from rejected independent claim 10.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

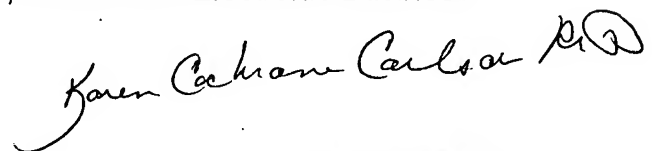
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-273-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR



KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER